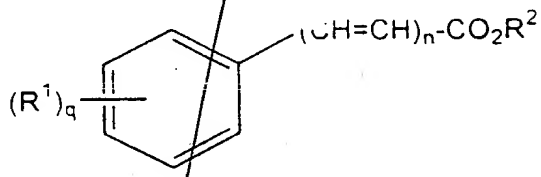
THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. A transdermal drug delivery system which comprises at least one physiologically active agent or prodrug thereof and at least one dermal penetration enhancer; characterised in that the dermal penetration enhancer is a safe skin-tolerant ester sunscreen.

2. A drug delivery system according to claim 1, characterised in that said ester is of formula (I):



(I)

wherein R^1 is hydrogen, lower alkyl, lower alkoxy, halide, hydroxy or NR^3R^4;

R^2 is long chain alkyl;

R^3 and R^4 are each independently hydrogen, lower alkyl or R^3 and R^4 together with the nitrogen atom to which they are attached form a 5- or 6-membered heterocyclic ring;

n is 0 or 1; and

q is 1 or 2.

3. A drug delivery system according to claim 1 or claim 2, characterised in that said ester is a long chain alkyl para-aminobenzoate, long chain alkyl dimethyl-para-aminobenzoate, long chain alkyl cinnamate, long chain alkyl methoxycinnamate or long chain alkyl salicylate.

4. A drug delivery system according to claim 3, characterised in that said ester is octyl dimethyl-para-aminobenzoate, octyl para-methoxycinnamate or octyl salicylate.

5. A drug delivery system according to any one of claims 1 to 4, further comprising a pharmaceutical compounding agent, co-solvent, surfactant, emulsifier, antioxidant, preservative, stabiliser, diluent or a mixture of two or more of said components.

6. Use of a safe skin-tolerant ester sunscreen as a dermal penetration enhancer.

7. Use according to claim 6, characterised in that the ester is of formula (I) as defined in claim 2.

8. Use according to claim 6 or claim 7, characterised in that the ester is long chain alkyl para-aminobenzoate, long chain alkyl dimethyl-para-aminobenzoate, long chain alkyl cinnamate, long chain alkyl methoxycinnamate or long chain alkyl salicylate.

9. Use according to any one of claims 6 to 8, characterised in that the ester is octyl dimethyl-para-aminobenzoate, octyl para-methoxycinnamate or octyl salicylate.

10. A transdermal drug delivery system which comprises at least one physiologically active agent or prodrug thereof, at least one dermal penetration enhancer and at least one volatile liquid;
characterised in that the dermal penetration enhancer is a safe skin-tolerant ester sunscreen.

11. A non-occlusive, percutaneous or transdermal drug delivery system which comprises:

(i) an effective amount of at least one physiologically active agent or prodrug thereof;

(ii) at least one non-volatile dermal penetration enhancer; and

(iii) at least one volatile liquid;

characterised in that
the dermal penetration enhancer is adapted to transport the physiologically active agent

across a dermal surface or mucosal membrane of an animal, including a human, when the volatile liquid evaporates, to form a reservoir or depot of a mixture comprising the penetration enhancer and the physiologically active agent or prodrug within said surface or membrane; and

the dermal penetration enhancer is of low toxicity to, and is tolerated by, the dermal surface or mucosal membrane of the animal.

12. A drug delivery system according to claim 11, characterised in that the drug delivery system is not supersaturated with respect to the physiologically active agent or prodrug.

13. A drug delivery system according to claim 11 or claim 12, characterised in that after application of the system to an area of the dermal surface or mucosal membrane, the area becomes touch-dry.

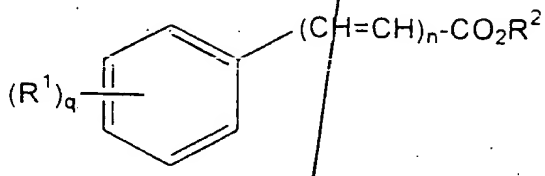
14. A drug delivery system according to claim 13, characterised in that the dermal surface or mucosal membrane becomes touch-dry within 10 minutes of application.

15. A drug delivery system according to claim 13, characterised in that the dermal surface or mucosal membrane becomes touch-dry within 3 minutes of application.

16. A drug delivery system according to claim 13, characterised in that the dermal surface or mucosal membrane becomes touch-dry within 1 minute of application.

17. A drug delivery system according to any one of claims 11 to 16, characterised in that the dermal penetration enhancer is a safe skin-tolerant ester sunscreen.

18. A drug delivery system according to claim 17, characterised in that said ester is of formula (I):



(I)

wherein R^1 is hydrogen, lower alkyl, lower alkoxy, halide, hydroxy or NR^3R^4;

R^2 is long chain alkyl;

R^3 and R^4 are each independently hydrogen, lower alkyl or R^3 and R^4 together with the nitrogen atom to which they are attached form a 5- or 6-membered heterocyclic ring;

n is 0 or 1; and

q is 1 or 2.

19. A drug delivery system according to claim 17 or claim 18, characterised in that said ester is a long chain alkyl para-aminobenzoate, long chain alkyl dimethyl-para-aminobenzoate, long chain alkyl cinnamate, long chain alkyl methoxycinnamate or long chain alkyl salicylate.

20. A drug delivery system according to claim 19, characterised in that said ester is octyl dimethyl-para-aminobenzoate, octyl para-methoxycinnamate or octyl salicylate.

21. A drug delivery system according to any one of claims 11 to 20, characterised in that the volatile liquid is ethanol or isopropanol.

22. A drug delivery system according to any one of claims 11 to 21, characterised in that the physiologically active agent is a steroid, hormone derivative, non-steroidal anti-inflammatory drug, opioid analgesic, antinauseant, antioestrogen, aromatase inhibitor, 5-alpha reductase inhibitor, anxiolytic, prostaglandin, anti-viral drug, anti-migraine compound, antihypertensive agent, anti-malarial compound, bronchodilator anti-depressant, anti-alzheimer's agent, neuroleptic and antipsychotic agent, anti-parkinson's agent, antiandrogen or anorectic agent.

23. A drug delivery system according to any one of claims 11 to 22, characterised in that the physiologically active agent is testosterone, oestradiol, ethinyloestradiol, progesterone, norethisterone acetate, ibuprofen, ketoprofen, flurbiprofen, naproxen, diclofenac, fentanyl, buprenorphine, scopolamine, prochlorperazine, metochlopramide, ondansetron, tamoxifen, epitiostanol, exemestane, 4-hydroxy-androstenedione and its derivatives, finasteride, turosteride, LY191704, MK-306, alprazolam, alprostadil, prostacylcin and its derivatives, melatonin, n-docosanol, tromantadine, lipophilic pro-drugs of acyclovir, low molecular weight heparin, enoxaparin, sumatriptan, amlodipine, nitrendipine, primaquine, minoxidil, minoxidil pro-drugs, pilocarpine, salbutamol, terbutaline, salmeterol, ibogaine, bupropian, rolipram, tacrine, fluphenazine, haloperidol, N-0923, cyproterone acetate or mazindol.

24. A drug delivery system according to any one of claims 11 to 23, characterised in that the system is applied to the dermal surface or mucosal membrane by an aerosol, as a spray.

25. A drug delivery system according to claim 24, characterised in that the aerosol is a fixed or variable metered dose aerosol.

26. A drug delivery system according to any one of claims 11 to 25, further comprising a pharmaceutical compounding agent, co-solvent, surfactant, emulsifier, antioxidant, preservative, stabiliser, diluent or a mixture of two or more of said components.

27. A method for administering at least one systemic or locally acting physiologically active agent or prodrug thereof to an animal which comprises applying an effective amount of the physiologically active agent in the form of a drug delivery system according to any one of claims 1 to 5 and 10 to 26 to a dermal surface or mucosal membrane of said animal.

28. A method for the treatment or prophylaxis of a disease or condition in an animal which comprises administering to a dermal surface or mucosal membrane of said animal in need of such treatment a therapeutically effective amount of the drug delivery system according to any one of claims 1 to 5 and 10 to 26 to a dermal surface or mucosal membrane of said animal.

29. A method according to claim 28, characterised in that the disease or condition requires male hormone replacement in testosterone deficient hypogonadal men, female hormone replacement therapy for postmenopausal women, androgen replacement therapy for females lacking libido, male contraception or female contraception.

30. A method according to claim 28, characterised in that the disease or condition is soft tissue injury, narcotic withdrawal, severe post-operative pain, motion sickness, oestrogen dependent breast cancer, prostatic enlargement and/or prostatic cancer, alopecia and acne, anxiety disorders, male impotence, Raynauds syndrome and varicose veins, sleep disorders, jetlag, herpes virus infections, deep vein thrombosis, migraine, high blood pressure, malaria, diagnosis of cystic fibrosis, asthma or nocturnal asthma.

31. A method according to any one of claims 27 to 30, characterised in that the animal is a human.

32. Apparatus for the controlled application of an aerosol or spray composition to the dermal surface or mucosal membrane of an animal, which comprises a shroud adapted to receive the actuator nozzle of the device whereby when the shroud is placed on an intended site of application, the shroud keeps the actuator nozzle at a pre-determined height above the site of application.

33. Apparatus according to claim 32, characterised in that the shroud keeps the actuator nozzle substantially perpendicular to the site of application.

34. Apparatus according to claim 32 or claim 33, characterised in that the shroud prevents or limits bounce-back when a composition is applied to the site of application by the actuator nozzle.

35. Apparatus according to any one of claims 32 to 34, characterised in that the shroud contains, within a volume defined by the shroud, spray from the actuator nozzle when a composition is applied to the site of application from the actuator nozzle.

36. Apparatus according to any one of claims 32 to 35, characterised in that the area of application defined by the shroud is substantially circular in shape.

37. Apparatus for the controlled application of an aerosol or spray composition to the dermal surface or mucosal membrane of an animal which comprises the combination of an aerosol or spray device and a shroud as claimed in any one of claims 32 to 36.

38. A method according to any one of claims 27 to 31, characterised in that the drug delivery system is applied by an apparatus according to any one of claims 32 to 37.